

**WHAT IS CLAIMED IS:**

- 1                    1.        A method of forming an intravascular device, comprising the steps  
2 of:  
3                    mounting an expanded PTFE liner over a first mandrel portion;  
4                    winding a reinforcing layer over the expanded PTFE liner after the  
5 mounting step; and  
6                    applying a first jacket over the reinforcing layer and expanded PTFE liner  
7 after the winding and mounting steps.
- 1                    2.        The method of claim 1, further comprising the steps of:  
2                    covering the jacket, reinforcing layer and expanded PTFE liner with a  
3 shrink tube;  
4                    fusing the coating layer to the expanded PTFE liner to form an integrated  
5 structure; and  
6                    removing the shrink tube after the fusing step.
- 1                    3.        The method of claim 1, wherein:  
2                    the applying step is carried out by positioning a tube of material over the  
3 reinforcing layer.
- 1                    4.        The method of claim 1, further comprising the steps of:  
2                    positioning an etched PTFE liner over a second mandrel portion; and  
3                    the winding step is carried out with the reinforcing layer being wound over  
4 the etched PTFE liner; and  
5                    the applying step is carried out with the jacket layer being positioned over  
6 the reinforcing layer and the etched PTFE liner after the winding step.
- 1                    5.        The method of claim 4, wherein:  
2                    the applying steps are carried out with the jacket layer having a first jacket  
3 section and a second jacket section, the first jacket section being positioned over the  
4 expanded PTFE liner and the second jacket section being positioned over the etched  
5 PTFE liner, the first jacket section having a durometer which is at least 30D less than the  
6 second jacket section.
- 1                    6.        The method of claim 5, wherein:

2 the applying steps are carried out with the first jacket section having a  
3 durometer which is at least 40D less than the second jacket section.

1 7. The method of claim 1, wherein:  
2 the positioning steps are carried out with the expanded PTFE liner having  
3 a porosity of 8-10 microns.

1 8. The method of claim 4, wherein:  
2 the first mandrel portion and second mandrel portion are part of the same  
3 mandrel.

1 9. The method of claim 1, further comprising the step of:  
2 inverting an end of the expanded PTFE liner at a distal end.

1 10. The method of claim 9, wherein:  
2 the inverting step is carried out to form an inverted portion of the  
3 expanded PTFE liner which extends longitudinally at least 0.5 mm from a distal end of  
4 the reinforcing element.

1 11. An intravascular device, comprising:  
2 a liner layer having a first liner section, the first liner section being made  
3 of expanded PTFE;  
4 a reinforcing layer wound over the liner layer; and  
5 a jacket positioned over the reinforcing layer and fused with the liner  
6 layer.

1 12. The device of claim 11, wherein:  
2 the liner has a second liner section, the second liner section being made of  
3 a material which is stiffer than the expanded PTFE of the first liner section.

1 13. The device of claim 12, wherein:  
2 the second liner section is made of etched PTFE.

1 14. The device of claim 13, wherein:  
2 the expanded PTFE has a porosity of 8-10 microns.

1                   15.    An intravascular device for accessing small diameter, tortuous  
2 vessels, comprising:

3                   a shaft having a stiffness transition zone, the stiffness transition zone  
4 extending 20 to 30 cm from the distal end, the stiffness of the device increasing no more  
5 than 600% over any 4 cm portion of the stiffness transition zone; and  
6                   at least one lumen extending through the shaft.

1                   16.    The device of claim 15, wherein:  
2                   the stiffness of the device increases no more than 500% over any 4 cm  
3 portion of the stiffness transition zone.

1                   17.    The device of claim 15 wherein:  
2                   the shaft has a liner portion which lines the at least one lumen, the liner  
3 portion comprising expanded PTFE.

1                   18.    The device of claim 17, wherein:  
2                   the liner portion also comprises etched PTFE.

1                   19.    The device of claim 15, wherein:  
2                   the lumen has a cross-sectional area through the distal portion of 0.77 to  
3 7.1 mm<sup>2</sup>.

1                   20.    The device of claim 15, wherein:  
2                   the lumen has a cross-sectional area through the proximal portion of 1.7 to  
3 2.9 mm<sup>2</sup>.

1                   21.    The device of claim 15, wherein:  
2                   the stiffness transition zone coincides with at least a portion of an  
3 intermediate, tapered region of the lumen.

1                   22.    The device of claim 21, wherein:  
2                   the proximal portion has a constant cross-sectional area;  
3                   the distal portion has a constant cross-sectional area; and  
4                   the intermediate section is tapered and extends between the proximal and  
5 distal portions.

- 1                   23.    The device of claim 15, wherein:  
2                   the distal portion has an expanded PTFE liner; and  
3                   the proximal portion has an etched PTFE liner.
- 1                   24.    The device of claim 15, wherein:  
2                   the distal portion has a wall thickness of 0.004 to 0.007 inch.
- 1                   25.    The device of claim 15, wherein:  
2                   the proximal portion has a wall thickness of between 0.003 to 0.013 inch.
- 1                   26.    The device of claim 15, wherein:  
2                   the distal portion is formed by a liner, at least one reinforcing element, and  
3                   a jacket over the liner and the reinforcing element, the jacket having a first section, a  
4                   second section, and a third section, the first section having a durometer which is at least  
5                   13D less than the third section, the second section having a durometer between the first  
6                   and third sections, the first and third sections being separated by a longitudinal distance of  
7                   10 cm or less.
- 1                   27.    The device of claim 26, wherein:  
2                   the first and third sections are separated by a longitudinal distance of 8 cm  
3                   or less.
- 1                   28.    The device of claim 26, wherein:  
2                   the shaft has a fourth section which is positioned next to the third section,  
3                   the first section having a durometer which is at least 25D less than the fourth section, the  
4                   first section being separated from the fourth section by a longitudinal distance of 15 cm or  
5                   less.
- 1                   29.    The device of claim 28, wherein:  
2                   the positioning step is carried out with the first section being separated  
3                   from the fourth section by a longitudinal distance of 10 cm or less.
- 1                   30.    A method of advancing an intravascular device into small diameter,  
2                   tortuous vessels, comprising the steps of:  
3                   providing a catheter having a lumen extending therethrough, the lumen  
4                   having a cross-sectional size of 0.77 to 7.1 mm<sup>2</sup>;

5                   introducing the catheter into the patient vascular system; and  
6                   advancing the catheter through vessels having a diameter of 3 mm to 5 mm  
7                   without advancing the catheter over a guidewire.

1                   31.     The method of claim 30, wherein:  
2                   the advancing step being carried out with the catheter having an open end  
3                   at the distal end.

1                   32.     The method of claim 30, wherein:  
2                   the providing step is carried out with the lumen having a cross-sectional  
3                   size of 1.7 to 2.9 mm<sup>2</sup>.

1                   33.     The method of claim 30, wherein:  
2                   the providing step is carried out with the catheter having a constant  
3                   diameter proximal portion, a tapered intermediate portion, and a constant diameter distal  
4                   portion.

1                   34.     The method of claim 30, wherein:  
2                   the providing step is carried out with the catheter having a stiffness  
3                   transition zone from 20-40 cm from the distal end, the stiffness of the catheter increasing  
4                   by no more than 600% over any 4 cm length through the stiffness transition zone.

1                   35.     A method of forming an intravascular device, comprising the steps  
2                   of:  
3                   providing a mandrel;  
4                   mounting a first liner on the mandrel;  
5                   winding a reinforcing layer over the first liner;  
6                   positioning a first jacket, a second jacket and a third jacket over the  
7                   reinforcing layer, the second jacket being positioned between the first and third jackets,  
8                   the first jacket having a durometer which is at least 13D less than the third jacket, the  
9                   second jacket having a durometer between the first and third jackets; and  
10                  fusing at least the first, second and third jackets to the liner to encase the  
11                  reinforcing layer between the first liner and the first, second and third jackets.

1                   36.     The method of claim 35, wherein:

2                   the positioning step is carried out with the first jacket having a durometer  
3   of at least 15 D less than the third jacket.

1                   37.    The method of claim 35, wherein:  
2                   the first and third jackets are separated by a longitudinal distance of 10 cm  
3   or less.

1                   38.    The method of claim 37, wherein:  
2                   the first and third jackets are separated by a longitudinal distance of 8 cm  
3   or less.

1                   39.    The method of claim 38, wherein:  
2                   the first and third jackets are separated by a longitudinal distance of 5 cm  
3   or less.

1                   40.    The method of claim 35, wherein:  
2                   the positioning step is carried out with a fourth jacket which is positioned  
3   next to the third jacket, the first jacket having a durometer which is at least 25D less than  
4   the fourth jacket.

1                   41.    The method of claim 40, wherein:  
2                   the positioning step is carried out with the first jacket being separated from  
3   the fourth jacket by a longitudinal distance of 15 cm or less.

1                   42.    The method of claim 40 wherein:  
2                   the positioning step is carried out with the first jacket being separated from  
3   the fourth jacket by a longitudinal distance of 10 cm or less.

1                   43.    The method of claim 35, wherein:  
2                   the positioning step is carried out with a fifth jacket which is positioned  
3   next to the fourth jacket, the first jacket having a durometer which is at least 28D less  
4   than the fourth jacket.

1                   44.    The method of claim 43, wherein:  
2                   the positioning step is carried out with the first jacket being separated from  
3   the fifth jacket by a longitudinal distance 20 cm or less.

1                   45.     The method of claim 43 wherein:  
2                   the positioning step is carried out with the first jacket being separated from  
3                   the fifth jacket by a longitudinal distance of 15 cm or less.

1                   46.     The method of claim 35, wherein:  
2                   the positioning step is carried out with a sixth jacket which is positioned  
3                   next to the fifth jacket, the first jacket having a durometer which is at least 40D less than  
4                   the sixth jacket.

1                   47.     The method of claim 46, wherein:  
2                   the positioning step is carried out with the first jacket being separated from  
3                   the sixth jacket by a longitudinal distance of 25 cm or less.

1                   48.     The method of claim 46 wherein:  
2                   the positioning step is carried out with the first jacket being separated from  
3                   the fifth jacket by a longitudinal distance of 20 cm or less.

1                   49.     An intravascular device, comprising:  
2                   a shaft having a lumen extending therethrough;  
3                   a reinforcing layer embedded in the shaft; and  
4                   the shaft having a first jacket, a second jacket and a third jacket covering  
5                   the at least one reinforcing element, the second jacket being positioned between the first  
6                   and third jackets, the first jacket having a durometer which is at least 13D less than the  
7                   third jacket, the second jacket having a durometer between the first and third jackets.

1                   50.     The device of claim 49, wherein:  
2                   the first jacket has a durometer of at least 15 D less than the third jacket.

1                   51.     The device of claim 49, wherein:  
2                   the first and third jackets are separated by a longitudinal distance of 10 cm  
3                   or less.

1                   52.     The device of claim 49, wherein:  
2                   the first and third jackets are separated by a longitudinal distance of 8 cm  
3                   or less.

1                    53.     The device of claim 52, wherein:  
2                    the first and third jackets are separated by a longitudinal distance of 5 cm  
3     or less.

1                    54.     The device of claim 49, wherein:  
2                    the shaft has a fourth jacket which is positioned next to the third jacket, the  
3     first jacket having a durometer which is at least 25D less than the fourth jacket.

1                    55.     The device of claim 54, wherein:  
2                    the first jacket being separated from the fourth jacket by a longitudinal  
3     distance of 15 cm or less.

1                    56.     The device of claim 54 wherein:  
2                    the first jacket is separated from the fourth jacket by a longitudinal  
3     distance of 10 cm or less.

1                    57.     The device of claim 49, wherein:  
2                    the shaft has a fifth jacket which is positioned next to the fourth jacket, the  
3     first jacket having a durometer which is at least 28D less than the fourth jacket.

1                    58.     The device of claim 57, wherein:  
2                    the first jacket is separated from the fifth jacket by a longitudinal distance  
3     20 cm or less.

1                    59.     The device of claim 57 wherein:  
2                    the first jacket is separated from the fifth jacket by a longitudinal distance  
3     of 15 cm or less.

1                    60.     The device of claim 49, wherein:  
2                    the shaft has a sixth jacket which is positioned next to the fifth jacket, the  
3     first jacket having a durometer which is at least 40D less than the sixth jacket.

1                    61.     The device of claim 60, wherein:  
2                    the first jacket is separated from the sixth jacket by a longitudinal distance  
3     of 25 cm or less.

1                    62.     The device of claim 60 wherein:

2                   the first jacket is separated from the sixth jacket by a longitudinal distance  
3 of 20 cm or less.

1                   63.     The device of claim 49, wherein:  
2                   the reinforcing layer has a braided portion, the braided portion having a  
3 first section, a second section and a third section, the first section has a pic which is at  
4 least 15 more than the third section..

1                   64.     The device of claim 63, wherein:  
2                   the third section is separated from the first section by no more than 15 cm.

1                   65.     The device of claim 63, wherein:  
2                   the third section is separated from the first section by no more than 10 cm.

1                   66.     The device of claim 63, wherein:  
2                   the reinforcing layer has a fourth section, the first section has a pic which  
3 is at least 30 pics more than the fourth section, the first section being separated from the  
4 fourth section by no more than 20 cm.

1                   67.     The device of claim 66, wherein:  
2                   the first section is separated by the fourth section by no more than 15 cm.

1                   68.     An intravascular device for accessing small, tortuous vessels,  
2 comprising:  
3                   a shaft having at least four sections of varying stiffness, the shaft  
4 becoming more stiff proximally; and  
5                   a lumen extending through the shaft.

1                   69.     The device of claim 68, wherein:  
2                   the shaft is formed by a liner, a reinforcing layer, and a jacket, the  
3 reinforcing layer being positioned between the liner and jacket.

1                   70.     The device of claim 69, wherein:  
2                   the at least four sections of varying stiffness are provided by varying the  
3 durometer of the jacket and a spacing between windings of the reinforcing layer.

1                   71.     The device of claim 69, wherein:

2 the shaft has at least five sections of varying stiffness.

1 72. The device of claim 69, wherein:

2 the shaft has at least six sections of varying stiffness.

1 73. A method of advancing a catheter through small, tortuous vessels,  
2 comprising the steps:

3 providing a catheter having a proximal portion and a distal portion, the  
4 distal portion extending at least 10 cm from the distal end and the proximal portion  
5 extending within 40 cm from the distal end or closer, the proximal portion being at least  
6 20 times stiffer than the distal portion, the catheter having a lumen with the lumen along  
7 the distal portion having a diameter of 0.040 to 0.060 inch;

8 introducing the catheter into a patient; and

9 advancing the catheter through the patient's vasculature to a desired site.

1 74. The method of claim 73, wherein:

2 the providing step is carried out with the proximal portion being at least 40  
3 times stiffer than the distal portion.

1 75. The method of claim 73, wherein:

2 the providing step is carried out with the proximal portion being at least 60  
3 times stiffer than the distal portion.

1 76. The method of claim 73, wherein:

2 the providing step is carried out with the lumen along the proximal portion  
3 having an inner diameter of 0.070 to 0.010 inch.

1 77. The method of claim 72, wherein:

2 the advancing step is carried out with the distal portion being advanced  
3 through to the desired site without the aid of a guidewire.

1 78. A method of advancing a catheter into small diameter vessels,  
2 comprising the steps of:

3 providing a catheter having a distal portion and a proximal portion, the  
4 catheter also having a lumen extending through the proximal and distal portions, the  
5 lumen along the distal portion having an inner diameter of 0.040 to 0.050 inch;

6                   introducing the catheter into a patient's vascular system; and  
7                   advancing the catheter through vessels having a size of less than 5 mm  
8   without the aid of a guidewire.

1                   79.    The method of claim 77, wherein:  
2                   the providing step is carried out with the distal portion extending at least  
3   10 cm from a distal end and the proximal portion extending within 40 cm from the distal  
4   end or closer.

1                   80.    The method of claim 78, wherein:  
2                   the proximal portion has a stiffness which is at least 40 times stiffer than  
3   the proximal portion.

1                   81.    The method of claim 78, wherein:  
2                   the proximal portion has a stiffness which is at least 60 times stiffer than  
3   the proximal portion.

1                   82.    The method of claim 77, wherein:  
2                   the providing step is carried out with the lumen along the proximal portion  
3   having an inner diameter of 0.070 to 0.100 inch.

1                   83.    The method of claim 77, wherein:  
2                   the advancing step is carried out with the distal portion being advanced  
3   through vessels having a size of less than 4 mm.

1                   84.    A method of forming a catheter, comprising the steps of:  
2                   providing a liner layer;  
3                   wrapping a reinforcing layer over the liner;  
4                   positioning a jacket over the reinforcing layer, the jacket having a plurality  
5   of jacket sections increasing in flexural modulus at least 25 times from a distal section to  
6   a proximal section.

1                   85.    The method of claim 83, wherein:  
2                   the positioning step is carried out with the jacket sections increasing in  
3   flexural modulus at least 40 times.

1                   86.    The method of claim 83, wherein:

- 2 the positioning step is carried out with increase in flexural modulus
- 3 occurring over a length of at least 15 cm.